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UTILITY PATENT APPLICATION TRANSMITTAL
(Large Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No. 1062/C30

Total Pages in this Submission 47 49

11/17/00 Jc957 U.S. PTO

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TO THE COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

and invented by:

Gray et al

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: 08/917,537

Which is a:

☐ **Continuation** ☐ **Divisional** ☒ **Continuation-in-part (CIP)** of prior application No.: 08/478,065

Which is a:

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 21 pages and including the following:
   a. ☒ Descriptive Title of the Invention
   b. ☒ Cross References to Related Applications *(if applicable)*
   c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   d. ☐ Reference to Microfiche Appendix *(if applicable)*
   e. ☒ Background of the Invention
   f. ☒ Brief Summary of the Invention
   g. ☒ Brief Description of the Drawings *(if drawings filed)*
   h. ☒ Detailed Description
   i. ☒ Claim(s) as Classified Below
   j. ☒ Abstract of the Disclosure

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47

Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
   a. ☒ Formal Number of Sheets 14
   b. ☐ Informal Number of Sheets _____
4. ☒ Oath or Declaration
   a. ☐ Newly executed *(original or copy)* ☐ Unexecuted
   b. ☒ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
   c. ☒ With Power of Attorney ☐ Without Power of Attorney
   d. ☐ *DELETION OF INVENTOR(S)*
   Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☒ Incorporation By Reference *(usable if Box 4b is checked)*
   The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ Computer Program in Microfiche *(Appendix)*
7. ☐ Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all must be included)*
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy *(identical to computer copy)*
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☐ Assignment Papers *(cover sheet & document(s))*
9. ☐ 37 CFR 3.73(B) Statement *(when there is an assignee)*
10. ☐ English Translation Document *(if applicable)*
11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Acknowledgment postcard
14. ☒ Certificate of Mailing
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UTILITY PATENT APPLICATION TRANSMITTAL
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Docket No.
1062/C30
Total Pages in this Submission
47

Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☐ Additional Enclosures *(please identify below):*

Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra		Rate	Fee
Total Claims	21	- 20 =	1	x	$18.00	$18.00
Indep. Claims	4	- 3 =	1	x	$80.00	$80.00
Multiple Dependent Claims (check if applicable) ☐						$0.00
					BASIC FEE	$710.00
OTHER FEE *(specify purpose)*						$0.00
					TOTAL FILING FEE	$808.00

☒ A check in the amount of **$808.00** to cover the filing fee is enclosed.

☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **19-4972** as described below. A duplicate copy of this sheet is enclosed.

- ☐ Charge the amount of as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Herbert A. Newborn

Signature

Dated: **November 17, 2000**

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): **Gray et al.**			Docket No. **1062/C30**
Serial No. **N/A**	Filing Date **filed herewith**	Examiner **N/A**	Group Art Unit **N/A**

Invention: **CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM**

I hereby certify that this **New Utility Patent Application Cover Sheet and Enclosures Referred to Therein**
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Note: Each paper must have its own certificate of mailing.

INITIAL INFORMATION DATA SHEET

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APPLICATION INFORMATION

Title Line One:	Cassette for Intravenous-Line
Title Line Two:	Flow-Control System
Total Drawing Sheets:	14
Application Type:	Utility
Docket Number:	1062/C30
Secrecy Order in Parent Appl.?	No

REPRESENTATION INFORMATION

Representative Customer Number: 2101

CONTINUITY INFORMATION

This application is a:	Continuation of
> Application One:	08/917,537
Filing Date:	August 22, 1997
which is a:	Continuation in part of
>>Application Two:	08/478,065
Filing Date:	June 7, 1995
Patent Number:	5,755,683

Attorney Docket: 1062/C30

CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

DESCRIPTION

Related Applications

The present application is a continuation of U.S. application serial No. 08/917,537 filed August 22, 1997, which, in turn, is a continuation-in-part of U.S. application serial no. 08/478,065 filed June 7, 1995, which issued as U.S. Patent No. 5,755,683 on May 26, 1998, which was concurrently filed with applications serial no. 08/472,212, entitled "Intravenous-Line Flow-Control System" for an invention by Heinzmann, Kamen, Lanigan, Larkins, Lund and Manning, which issued on June 30, 1998 as U.S. Patent No. 5,722,637; serial no. 08/481,606, entitled "Intravenous-Line Air-Elimination System" for an invention by Manning, Larkins, Houle, Kamen and Faust, which issued on February 3, 1998 as U.S. Patent No. 5,713,865; and serial no. 08/477,380, entitled "Intravenous-Line Air-Detection System" for an invention by Larkins, Beavis and Kamen, which issued on June 24, 1997 as U.S. Patent No. 5,641,892. All of these related applications are hereby incorporated herein by reference.

Technical Field

The present invention relates to apparatus and methods for controlling flow through an intravenous line.

Summary of the Invention

The invention is directed to a cassette for controlling the flow of IV fluid from a patient to a source. The cassette preferably includes, along the fluid passage through the cassette, first and second membrane-based valves on either side of a pressure-conduction chamber, and a stopcock-type valve. The stopcock valve is preferably located downstream of the second membrane-based valve, which is preferably located downstream of the pressure-conduction chamber.

In a preferred version of the cassette, which is primarily made out of rigid material, the membrane for the second membrane-based valve is disposed adjacent the housing, such that the rigid housing and the membrane define a valving chamber. One passage enters the valving chamber at a first mouth located at the end of a protrusion of the rigid housing into the valving chamber towards the membrane, and the valve may prevent the flow of fluid therethrough when the membrane is forced against the first mouth, by the control unit. The control valve restricts the flow of intravenous fluid from the valving chamber to the patient, since it is located downstream of the valving chamber. The membrane defining the valving chamber is preferably large and resilient, so that the valving chamber may provide a supply of pressurized intravenous fluid to the patient, when the first mouth is sealed closed and when there is a restriction downstream of the valving chamber.

For the pressure-conduction chamber, a membrane is preferably disposed adjacent the rigid housing, so as to define a pressure-conduction chamber, wherein the rigid housing portion that defines the pressure-conduction chamber is generally dome-shaped. The membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is at its smallest volume, and in which position the membrane rests against the rigid housing and assumes the dome shape of the rigid housing. The membrane preferably has a structure for creating instability in the membrane in the filled-chamber position. Preferably, this structure may be actuated to create instability in the membrane in the empty-chamber position. The rigid housing and the second membrane in the empty-chamber position preferably define an unobstructed fluid passageway through the pressure-conduction chamber from the first to the second pressure-conduction chamber mouth. Preferably, the structure for creating instability in the membrane causes the membrane, when its at its full-chamber position, to collapse in the region of the pressure-conduction chamber's outlet mouth before collapsing nearer the inlet mouth. This structure helps force bubbles in the fluid upward toward the inlet mouth and the IV fluid source during a bubble-purge cycle.

Brief Description of the Drawings

FIG. 1 shows a top view of a cassette according to a preferred embodiment of the

present invention.

FIGS. 2 and 3 show front and bottom views respectively of the cassette of FIG. 1.

FIG. 4 shows a control unit for receiving and controlling a cassette, such as the cassette of FIGS. 1 - 3.

FIG. 5 shows a cross-section of the cassette of FIGS. 1 - 3.

FIG. 6 shows a rear view of the cassette and shows the fluid paths through the cassette.

FIG. 7 shows a front view of the middle rigid panel of the cassette of FIGS. 1 - 3.

FIGS. 8 and 9 show side and rear views respectively of the middle panel of FIG. 7.

FIG. 10 shows a partial cross-section of the middle panel of FIG. 7.

FIG. 11 is a cross-sectional detail of the control valve of the cassette according to a preferred embodiment of the invention.

FIG. 12 shows a side view of an outer cylinder (a valve-seat member) having rigid and resilient elements that may be used in the control valve.

FIG. 13 shows a cross-sectional view of the cylinder of FIG. 12.

FIG. 14 depicts the relationship between the aperture of the FIG. 12 cylinder and the groove used in the control valve.

FIG. 15 shows a cross-sectional view of the membrane that may be used in the pressure-conduction chamber of the cassette shown in FIG. 1.

FIGS. 16 and 17 show front and rear views respectively of the FIG. 15 membrane.

FIG. 18 shows a front view of the membrane used in the valve located downstream of the pressure-conduction chamber and upstream of the control valve.

FIG. 19 shows a cross-section of the FIG. 18 membrane.

FIG. 20 is a schematic representing how the compliant membrane of FIG. 18 may be used to regulate the pressure of fluid to the patient.

FIG. 21 is a graph depicting the advantage of using a compliant membrane such as that shown in FIG. 18.

FIGS. 22 and 23 depict the preferred shape of the inlet valve to the pressure conduction chamber.

FIG. 24 shows a cross-sectional view of the inlet valve to the pressure conduction chamber.

FIG 25 shows a preferred arrangement of teeth around the circumference of the

control wheel.

FIG. 26 shows a front view of a cassette according to an alternative preferred embodiment of the present invention.

FIG. 27 shows a front view of the membrane that may be used in the pressure-conduction chamber of the cassette shown in FIG. 26.

FIG. 28 shows a cross-sectional view of the membrane shown in FIG. 27 along line B-B.

FIG. 30 shows a cross-sectional view of the membrane shown in FIG. 27 along line A-A.

FIG. 31 shows a perspective view of an alternative cassette which may use the membrane shown in FIGS. 27-30.

Detailed Description of Specific Embodiments

The present invention includes a cassette for use in a system for controlling the flow of IV fluid to a patient, along the lines of the cassettes disclosed in U.S. Patents Nos. 5,088,515 and 5,195,986. A preferred embodiment of the cassette is depicted in FIGS. 1 - 3, which respectively depict top, front and bottom views of the cassette. The cassette is used in a control unit, such as that described in above-referenced U.S. Patent No. 5,772,637, entitled "Intravenous-Line Flow-Control System," which is similar to the control unit described in U.S. Patent No. 5,088,515, which describe the use of pressure, preferably pneumatic pressure, for controlling the actuation of valves and the urging of fluid into and out of a pressure-conduction chamber. In addition to performing the function of a pump urging fluid through the IV line, the pressure-conduction chamber can measure the amount of IV fluid being delivered to the patient as well as detect the presence of bubbles in the IV fluid in the pressure-conduction chamber. Preferred methods of detecting and eliminating air bubbles from the IV fluid are discussed in the above-referenced patent applications for "Intravenous-Line Air-Detection System" and "Intravenous-Line Air-Elimination System," now U.S. Patent Nos. 5,641,982 and 5,713,865, respectively. FIG. 4 depicts a preferred version of a control unit **10**. Control unit **10**, which has a user-interface panel **103** containing a key pad and a display so that the status of the IV fluid delivery may be monitored and modified by medical personnel.

The cassette is slipped behind door **102**, and by turning handle **101** the door is pressed against the cassette, which in turn is then pressed against the main housing of the control unit **10**. The main housing **104** preferably includes mechanical means for actuating membrane-covered valves and for applying a pressure against the membrane of the pressure-conduction chamber. The main housing **104** also includes means for turning the control wheel of the cassette.

Referring to FIG. 2, the main components of the preferred embodiment of the cassette are a first membrane-based valve **6**, a pressure-conduction chamber **50**, a second membrane based valve **7** and a stopcock-type control valve **20**. Valve **6** controls the flow to the pressure-conduction chamber **50** from the inlet **31** to the cassette, which is connected to an IV line, which in turn is connected to a source of IV fluid. The second membrane-based valve **7** and the control valve **20** together are used to control the flow of fluid from the pressure-conduction chamber **50** to the outlet to the cassette **33**, which is connected to the IV line leading to the patient.

The rigid housing **15** of the cassette is made primarily from three rigid panels. A front panel **17**, a middle panel **18**, and a rear panel **16**, all three of which can be seen in FIGS. 1 and 3. The front panel is preferably molded integrally with the outer collar **21** of the control valve **2**. The wheel **20** of the control valve **2** preferably includes ribs **281** and/or teeth mounted along the circumference **29** of the knob **20**. (FIG. 25 shows a preferred arrangement of teeth around the circumference **29** of the control knob **20**.) The teeth and/or ribs **281** may be engaged by the main housing **104** of the control unit **10**, so that the control unit **10** may change the resistance that the control valve **2** exerts on the IV fluid passing through the valve.

The cassette may also be used without the control unit **10**. In that case, the control wheel **20** may be turned by hand. When disengaged from the control unit **10**, the membrane of the pressure-conduction chamber **50** is preferably collapsed so that it rests against the rigid rear wall **59** of the pressure-conduction chamber **50**. With the membrane in this collapsed state, IV fluid may still easily flow through the pressure-conduction chamber **50** through a raised portion **35** of the rear wall **59**. This raised portion **35** defines a conduit **36** leading from the inlet mouth of the pressure-conduction chamber **50** to the

outlet mouth of the pressure-conduction chamber, as can be seen in FIG. 6. FIG. 6 shows the fluid paths leading through the cassette. As noted above, fluid enters the cassette through the inlet **31**, whence it flows through a fluid path to valve **6**. The fluid then enters the valving chamber of valve **6** through an inlet port **62**. An outlet port **61** is preferably mounted on a protrusion so that pressure from the pressure-conduction chamber **50** is less likely to force the membrane to lift from the outlet port **61**. From valve **6** the fluid passes to the inlet mouth **56** of the pressure-conduction chamber **50**. The pressure-conduction chamber is seen in the cross-sectional view of FIG. 5. A membrane **41** allows pressure from the control unit **10** to be applied to the fluid in the pressure-conduction chamber **50** without the fluid coming into contact with the control unit **10**. When the membrane **41** is in its collapsed position resting against rigid wall **59**, as shown in FIG. 5, fluid can still pass from inlet valve **56** through conduit **36** to the outlet valve **57**. After passing through the pressure-conduction chamber **50**, the fluid flows to the second membrane-based valve **7**, which included an inlet mouth **73**, which is mounted on a protrusion **72** in similar fashion to the outlet port **61** of the first membrane-based valve **6**. The second membrane-based valve's inlet mouth**73** and the protrusion **72** on which it is mounted can be seen in the cross-sectional view of FIG. 5. Like the outlet port **61** of the first membrane-based valve, the inlet mouth **73** may be closed by the application of pressure by the control unit **10** on a membrane; a first portion **71** of the membrane that closes off the inlet mouth **73** can be seen in FIG. 5. After passing through the outlet mouth **76** of the second membrane-based valve **7**, the fluid passes to the inlet **77** of the stopcock-type control valve, which inlet can be seen in both FIGS. 5 and 6. After passing through the control valve and the fluid path **78** exiting from the control valve, the fluid passes to the outlet of the cassette **33** and to the IV line leading to the patient.

FIG. 7 shows a front view of the rigid middle portion of the cassette, and FIG. 8 shows a side view of the middle rigid panel **18**. The middle rigid panel **18** defines the cassette inlet **31** and outlet **33**, a circumferential portion of the pressure-conduction chamber **50**, and port **62**, outlet port **61**, inlet mouth **73**, and outlet mouth **76** of the two membrane-based valves **6** and **7**. The protrusions **63** and **72** of the outlet port **61** and inlet mouth **73** can also be seen in FIG. 7. FIG. 9 shows a rear view of the middle rigid panel

18 shown in FIGS. 7 and 8. The ports/mouths **61**, **62**, **73**, **76** can also be seen in FIG. 9. FIG. 10 shows a partial cross-section of the middle rigid portion. The cross-section shows the outer collar **21** of the control valve, which is integrally molded with the rest of the middle rigid portion. The outer collar **21** defines a hollow area **22** and a fluid path **23** leading from the hollow area **22**.

FIG. 11 shows a cross-section of an assembled control valve **2** that may be used in a cassette according to the present invention. Just inside of the outer collar **21** is a valve-seat member **22** fixedly attached to the outer collar **21** so that the valve-seat member **21** does not rotate with respect to the rest of the cassette. The valve-seat member **21** is depicted in greater detail in FIG. 12 and in cross-section in FIG. 13. The valve-seat member **22** also defines a hollow area, which accepts the shaft **220** of the control wheel **20**, so that the control wheel's shaft**220** rotates with the control wheel **20**. The valve-seat member **22** is comprised mostly of rigid material, but importantly it also includes molded-over resilient material, which is used to form sealing O-rings. This resilient material forms an O-ring **26** around the base of the valve-seat member **22**; the rigid portion of the base defines a passage **222**, connecting the valve inlet **77** to passage **24**. The resilient material **25** also provides a seal around an aperture **251** in the circumferential surface of the member **22**. At the end of the member **22** opposite the inlet passage **222** is an inner O-ring **27** which forms the seal between the control wheel's shaft**220** and the valve-seat member **22**. The O-ring **26** around the exterior circumference of the base provides a seal between the outer circumferential wall of the valve-seat member **22** and the inner circumferential wall of the outer collar **21**. Likewise, the O-ring **25** around the circumferential port **251** may provide a seal between the outer circumferential wall of the valve-seat member **22** and the inner circumferential wall of the outer collar **21**. Together, O-rings **25**, **26** prevent fluid from leaking between the valve-seat member **22** and the outer collar **21**. Importantly, the O-ring **25** of port **251** also provides a seal between the valve-seat member **22** and the shaft **220**, so that when the valve is in the fully closed position no flow is permitted between passageway **24** of shaft **220** and the port **251** of the valve-seat member **22**.

The advantage of this design over previous stopcock valves is that the outer

diameter of the shaft **220** may be slightly less than the inner diameter of the valve-seat member **22**, whereas previous stopcock valves required an interference fit between the inner and outer components. It will be appreciated that the stopcock valve of the present invention may use frusto-conical-shaped members instead of cylindrical members. The interference fit of prior-art devices created a great deal of resistance when the stopcock valves were turned. The use of O-rings in the stopcock valve of the present invention avoids the need for this interference fit and the greater torque required for turning the valve resulting from the interference fit. O-ring **27** prevents leaking from the space between the valve-seat member **22** and the shaft of the control wheel **20**.

The valve-seat member is preferably made in a two-part molding process, wherein the rigid portion is first molded and then the softer resilient material is over-molded onto the rigid portion. Channels may be provided in the initially molded rigid portion so that the resilient material may flow to all the desired locations; this results in columns of resilient material **28** connecting the areas of resilient material through these channels. The valve-seat member **22** is preferably molded separately from the rest of the cassette, and when the cassette is assembled the valve-seat member **22** is placed in the hollow defined by the outer collar **21** of the middle panel **18**, and aligned so that aperture **251** lines up with passageway **23**. (The shape of the outer diameter of the valve-seat member **22** and the inner diameter of the outer collar **21** may be complementarily shaped so that the valve-seat member must align properly with the aperture **251** and the passageway **23** lined up.) Then, the front rigid panel **17** is ultrasonically welded (along with the rear rigid panel **16**) to the middle rigid panel **18**, and the valve-seat member **22** is then held in place in the hollow area defined by the outer collar **21**. The outer circumference of the valve-seat member **22** may be a bit smaller than the inner diameter of the outer collar **21**; O-rings **25**, **26** prevent fluid from flowing from the passages **77** or **23** to point **19**. This design of the valve-seat member **22** avoids the need for tight tolerances in the various components of the valve **2**. The control wheel's shaft**220** may be inserted into the hollow area defined by valve-seat member **22** after the rest of the valve has been assembled. The shaft **220** is held in place by a lip **161**around the inner circumference of the hollow area defined by the rear rigid panel **16**

When the valve **2** is fully opened, the circumferential aperture **251** is lined up with

the fluid passage **24** in the shaft **220**. When the valve is fully closed there is no fluid communication between the aperture **251** and the fluid passage **24**. The outer circumferential surface of the shaft **220** preferably includes a groove extending circumferentially around the shaft's outer circumferential wall from the terminus of the fluid passage **24** at the outer circumferential wall; the groove tapers in cross-sectional area and does not extend all the way around the outer circumference of the shaft **220**. The groove provides greater control of the flow rate. FIG. 14 shows the respective locations of the groove **231**, which is located on the outer circumference of the shaft **220** and the circumferential aperture **251** of the valve seat member **22**. As the aperture **251** rotates to the right, in the FIG. 14 perspective, the resistance to flow increases, until the groove **231** ends and the aperture **251** loses fluid communication with the groove **231**, at which point flow is completely shut off through the control valve **2**. As the aperture **251** rotates to the left, in the FIG. 14 perspective, the resistance to flow decreases. Preferably, the groove **231** is longer than the diameter of the aperture **251**, so that the flow rate may be controlled more finely.

As noted above, the cassette may be used independently of the control unit **10**. When the cassette is used in this manner it is preferable that the membrane **41** rest against the rigid back **59** of the pressure-conduction chamber **50** so as to minimize the volume of the conduit **36** for fluid passing through the pressure conduction chamber **50**. If the membrane **41** were too flexible and the volume of the pressure-conduction chamber **50** varied widely, medical personnel would be unable to rely on a quick visual inspection of the rate of dripping in the drip chamber to indicate a steady, desired flow rate through the IV line. Thus, it is desired that the structure of the membrane **41** be such that it tends to rest against wall **59** unless and until a sufficient pressure differential is created across the diaphragm **41**. This pressure differential is preferably caused by a negative gas pressure caused by the control unit **10**. Although it is desired to manufacture the diaphragm **41** so that it has some tendency to rest against wall **59**, it is desired to make the diaphragm **41** floppy in the other direction so that less pressure is required to move it from its position when the pressure-conduction chamber **50** is full, the "filled-chamber" position. It is also desired that the measurement gas provided by the control unit **10** against the outer face of

the membrane **41** be at substantially the same pressure as the fluid on the inner side of the membrane **41** in the pressure-conduction chamber **50**.

By molding the diaphragm **41** in the shape of a dome corresponding to that of the rigid wall **59**, the diaphragm will have a tendency to remain in its position, as shown in FIG. 5, resting against wall **59** when the chamber **50** is at its lowest volume, the "empty-chamber" position. However, when the diaphragm **41** is molded in this way, it also tends to remain in the filled-chamber position, in other words, when the diaphragm **41** is bulging convexly outward from the cassette. This convex, filled-chamber position can be made unstable by adding additional material on the outer, usually concave surface of the diaphragm **41**. This additional material **43** can be seen in the cross-section of a preferred embodiment of the diaphragm as shown in FIG. 15. The diaphragm **41** shown in FIG. 15 is molded in the position shown and has a tendency to remain in that position. When the chamber is filled with fluid, the normally concave side of the diaphragm becomes convex, and the additional material **43** is subject to an additional amount of strain since it is at the outer radius of this convex, filled-chamber position. The diaphragm **41** shown in FIG. 15 also includes an integrally molded O-ring **44** around its circumference for mounting and sealing the diaphragm **41** in the cassette. FIG. 16 shows a view of the exterior side of the diaphragm **41** of FIG. 15. This surface of the diaphragm **41** is normally concave when the diaphragm is in the empty-chamber position. The additional material **43** can be seen in the view of FIG. 16. FIG. 17 shows the interior side of the diaphragm **41** of FIG. **15**. This side is normally convex when the diaphragm **41** is in the empty-chamber position. Thus, as a result of molding the diaphragm so that its inner surface has a smooth constant radius and the outer surface has additional material, which thereby interrupts the smoothness and constant radius of the rest of the outer face of the diaphragm, the diaphragm **41** has the desired tendency to remain in the empty-chamber position while being unstable in the filled-chamber position.

By positioning this additional material **43** near the outlet mouth **57** of the pressure-conduction chamber **50**, the collapse of the diaphragm **41** from its filled-chamber can be somewhat controlled so that the diaphragm tends to collapse first in the lower portion of the pressure-conduction chamber near the outer mouth **57** before further collapsing in the upper region of the pressure conduction chamber nearer the inlet mouth **56**. The cassette

is preferably mounted in the control unit with a slight tilt so that the passage **36** is vertical and the inlet mouth **56** is at the very top of the chamber **50** and the outlet mouth **57** is at the very bottom of the chamber **50**. This orientation permits the bubbles that may be present in the chamber **50** to gravitate towards the inlet mouth **56**, which is at the top of the chamber. In a preferred method of eliminating the bubbles from the IV fluid, as described in the above-referenced, concurrently filed application for "Intravenous-Line Air-Elimination System," any bubbles that are detected by the control unit in the pressure conduction chamber **50** are forced by pressure from the control unit against the external surface of the membrane **41** up to the inlet mouth **56** to the cassette inlet **31** up the IV line to the fluid source, sometimes after several purging and filling cycles. When purging the bubbles from the chamber **50** through the inlet mouth **56** it is preferred that the chamber collapse at its bottom first so that the membrane does not interfere with bubbles moving upwards through the chamber **50**.

Thus, the additional material **43** creates an instability in the membrane **41** when the membrane is in the filled-chamber position, thereby making the membrane more likely to collapse from the filled-chamber position than a membrane that did not have the additional material. The additional material **43**, however, does not create an instability in the membrane **41** when the membrane is in the empty-chamber position. In many situations it is desirable to be able to introduce some instability into the membrane when the membrane is in the empty-chamber position. By introducing such instability into the membrane, less negative pressure is needed to move the membrane from its empty-chamber position.

To create an instability in the empty-chamber position, a pressure-relief tab **143** may be added to the membrane **141** as shown in FIG. 26. The pressure-relief tab **143** extends from the exterior surface **145** near the edge of the membrane **141**, as can be seen in the cross-sectional view of FIG. 29. FIG. 28 shows another cross-sectional view, which view does not pass through the pressure-relief tab **143**, and FIG. 27 shows a front view of the membrane **141**. The tab **143** may be actuated by an actuator **149** (shown in FIG. 30) mounted in the control unit. When it is desired to introduce instability into the membrane--which will typically be whenever it is desired to fill a previously empty chamber **50**--the actuator **143** forces the tab **143** towards the O-ring **144**. This action pulls

the portion of the membrane **141** near the tab **143** away from the cassette's rigid wall, which partially defines the pressure-conduction chamber **50**. The tab **143** is located near the inlet mouth of the chamber **50** so that, when the actuator **149** pulls a portion of the membrane **141** away from the rigid wall, a pocket of space is formed into which the fluid can flow. By supplying a negative pressure to the exterior surface **145** of the membrane **141**, the control unit may cause more liquid to be drawn into the pressure-conduction chamber **50**. Less negative pressure is needed to move the membrane **141** out of the empty-chamber position, when the actuator **149** has urged the tab **143** towards the O-ring **144** and the rigid portion **117** of the cassette adjacent the tab **143**.

If it is desired to make the membrane **141** stable in the empty-chamber position, the control unit may cause the actuator **149** to be returned to the non-actuating position, so that the tab **143** may return to its normal position, extending outwardly from the cassette. As noted above, when the membrane is in the empty-chamber position, IV fluid may flow through the pressure-conduction chamber **50** through a conduit defined by raised portion of the rear wall (see FIGS. 3, 5 and 6) and leading from the inlet mouth of the pressure-conduction chamber **50** to the outlet mouth of the pressure-conduction chamber.

The pressure-reduction tab **143** also creates an instability in the filled-chamber position. When the pressure-conduction chamber **50** is filled with liquid, the exterior surface **145** of the membrane **141** becomes convex, rotating the tab **143** towards the O-ring **144**, so that the tab **143** is urged against the rigid portion **117** of the cassette. In this position, the tab **143** creates pressure on a portion of the membrane **141** so as to make the membrane less stable in the filled-chamber position so that the control unit needs to create less positive pressure to collapse the membrane **141** from its filled-chamber position.

FIG. 31 shows a cassette **215** that may be used in a bed-side pharmacy system, such as that described in the concurrently filed patent application for "System, Method and Cassette for Mixing and Delivering Intravenous Drugs" bearing attorney docket number 1062/B52, assigned serial no. 08/916,890, and which lists Kamen, Grinnell, Mandro, Gilbreath, Grant, Demers, Larkins and Manning as inventors, now abandoned in favor of continuation-in-part application, assigned serial no. 09/137,025 which application is incorporated herein by reference. Such a cassette may also use a membrane **241** having

a pressure-reduction tab **243**, which creates some instability in the filled-chamber position and which may be actuated to create some instability in the empty-chamber position.

Returning to the cassette **15** shown in FIGS. 1-3, a preferred membrane design for the second membrane-based valve **7** is shown in FIGS. 18 and 19. This membrane has an O-ring **78** for mounting and sealing the inlet; membrane onto the cassette (like the lip **44** on the membrane **41** for the pressure-conduction chamber, and like the circular membrane, which is not shown, for the first membrane-based valve **6**). This membrane has a first portion **71**, which is used to seal off the inlet mouth **73** located on protrusion **72** (see FIG. 5). The control unit **10** exerts a pressure against this portion of the membrane **71** mechanically, in order to close off the valve **7**. A second compliant portion **74** of the membrane is sufficiently compliant so that when the control valve **2** is sufficiently restricting flow out of the outlet **76** of the second membrane-based valve **7**, the compliant portion **74** of the membrane will expand outwardly so as to hold, under pressure, a volume of IV fluid. This design is desirable so that when the inlet mouth **73** is closed, because the pressure-conduction chamber needs to be refilled, the fluid stored in the valving chamber (item **75** in FIG. 5) is available to be dispensed through the control valve **2**.

FIG. 20 shows a schematic for an electrical model of the operation of the second membrane-based valve **7** working in conjunction with the stopcock-type control valve **20**. When the valve leading from the outlet **57** of the pressure-conduction chamber **50** is open, permitting flow from the pressure-conduction chamber through valve **7**, and if the stopcock valve **20** is set to provide a large amount of resistance to the flow from valve **7** to the patient, the valving chamber **75** and its corresponding compliant membrane portion **74** can accumulate a "charge" of fluid, much like a capacitor, as shown in FIG. 20. When first portion**71** is then urged against inlet mouth **73** closing off flow from the pressure-conduction chamber **50**, the charge of fluid in the valving chamber **75** is urged by the compliant membrane portion **74** to continue flow through the stopcock valve **20**. As fluid exits the valving chamber **75**, the pressure of the fluid decreases as the compliant portion **74** of the membrane returns to its unstretched state. FIG. 21 shows a graph depicting the pressure of the IV fluid being delivered to a patient over time as outlet valve **71, 73** is

closed at time t_1 and reopened at t_2. A solid line depicts the pressure to the patient without a compliant membrane portion **74** design. With a compliant membrane portion **74**, the sharp drop off in pressure at t_1 is eliminated or ameliorated. If the stopcock valve is nearly closed so that only a small trickle of fluid is allowed to flow through it, the design of the compliant membrane portion **74** will greatly smooth out the delivery of fluid, as long as the time between t_1 and t_2 is not too long. When the stopcock valve **2** is fully open a sharp drop in pressure may still be expected at time t_1.

As noted above (and as described in the above-referenced U.S. Patent No. 5,713,865, entitled "Intravenous-Line Air-Elimination System"), when an air bubble is being purged from the pressure-conduction chamber **50**, it is preferably forced up through the chamber's inlet valve**56** (which in this air-elimination mode is acting as an outlet). Preferably, the inlet port **56** is shaped so that a small bubble will not tend to stick to an edge of the port while allowing liquid to flow past it. To prevent such sticking of a small bubble, the port **56** preferably flares out so that the corner where the port **56** meets the inner wall of the pressure-conduction chamber **50** is greater than 90°, making the corner less likely a place where the bubble will stick. However, the mouth of the port **56** cannot be so large that liquid can easily flow by the bubble when fluid is exiting the pressure-conduction through the port **56**. In order to accomplish this, the port must be sized and shaped so that the surface tension of the IV fluid being forced upward from the pressure-conduction chamber **50** forces a bubble located at the port **56** up through the inlet valve **6**. It is also preferable that the port **56** be sized and shaped so that when liquid is pulled back into the pressure-conduction chamber **50**, the bubble can hover near the port as liquid passes around it. A preferred inlet port **56** shape is shown in FIGS. 22 and 23. The port's size increases from the end**57** that connects to the IV line's upper portion to the end **58** leading into the pressure-conduction chamber. FIG. 24 shows a cross-section of the inlet valve **56**. It has been found that providing an inlet port to the pressure-conduction chamber with this shape improves the air-elimination system's ability to purge bubbles from the chamber. Using a port such as that shown in FIGS. 22-24 in conjunction with the membrane **41** of FIGS. 15-17 helps force bubbles more quickly out of the pressure-conduction chamber when attempting to purge the bubbles back through the cassette's inlet **31** to the IV source.

FIG. 25 shows a preferred arrangement of teeth around the circumference **29** of the control wheel **20**. The teeth provide means for a gear in the control unit **10** to engage securely the control wheel's circumference--in particular, a gear that is used to prevent the free flow of fluid through the cassette when the cassette is removed from the control unit **10**. When the door **102** of the control unit **10** is being opened, the gear turns the control wheel **20** to close the stopcock-type valve **2**, thereby stopping all flow through the cassette and preventing free flow. To ensure that the gear does not continue turning the wheel **20** once the valve **2** has been closed off entirely, a sector **92** along the wheel's circumference is left free of teeth. When the wheel **20** is turned enough so that the gear is adjacent this toothless sector **92**, the valve **2** is fully closed. The lack of teeth prevents the gear from continuing to turn the wheel; thus, the wheel cannot be turned too much.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

What is claimed is:

1. A cassette for use in a system for controlling the flow of fluid downstream from a source to a patient, the cassette comprising:

first valving means located downstream from the source, the first valving means comprising a valving chamber; and

second valving means located downstream from the first valving means in line with the valving chamber and the patient;

wherein the first valving means, while sealed closed preventing fluid communication from the source, is adapted to urge a charge of pressurized fluid downstream from the valving chamber while the second valving means restricts flow to the patient.

2. A cassette according to claim 1, the first valving means further comprising:

a compliant membrane;

the membrane capable of controlling fluid communication with the source.

3. A cassette according to claim 2, wherein the membrane defines the valving chamber such that the valving chamber is expandable and capable of accepting and retaining the charge of fluid.

4. A cassette according to claim 3, wherein the charge is pressurized solely by a force exerted by the compliant membrane.

5. A cassette according to claim 1, the cassette further comprising:

pressure-conduction means located downstream from the source and upstream from the first valving means.

6. A cassette according to claim 5, the first valving means further comprising:

a compliant membrane;

the membrane capable of controlling fluid communication between the pressure conduction means and the second valving means.

7. A cassette according to claim 6, the pressure-conduction means further comprising:

a second membrane;

the second membrane defining a pressure-conduction chamber in fluid communication with the valving chamber.

8. A cassette for use in a system for controlling the flow of intravenous fluid from a

source to a patient, the cassette comprising:

a membrane-based valve comprising:

a rigid housing, having a first mouth, a first passage, a second mouth, and a second passage; and

a compliant membrane; and

a control valve located between the membrane-based valve and the patient;

the housing and the membrane coupled, defining a valving chamber, the first passage entering the valving chamber at the first mouth located such that flow of fluid via the first passage into the chamber may be prevented when the membrane is forced against the first mouth, the second passage exiting the valving chamber at the second mouth, so that a charge of pressurized fluid may be urged by the compliant membrane to continue flow from the valving chamber into the second passage via the second mouth toward and may be provided to the patient when both the membrane is forced against the first mouth and the control valve restricts fluid flow.

9. A cassette according to claim 8, further including:

a second membrane;

wherein the rigid housing and the second membrane are coupled so as to define a pressure-conduction chamber; the first passage providing fluid communication between the pressure-conduction chamber and the valving chamber.

10. A cassette according to claim 9, wherein a pressure-conduction chamber portion of the rigid housing is generally dome-shaped, the second membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is substantially at its smallest volume, and in which position the second membrane rests against the rigid housing and assumes the dome shape of the rigid housing, the second membrane having a structure for causing relative instability of the second membrane in the filled-chamber position.

11. A cassette according to claim 10, wherein the structure for causing relative instability in the filled-chamber position may be actuated to cause relative instability in the empty-chamber position.

12. A cassette according to claim 11, wherein the pressure-conduction chamber has a first pressure-conduction chamber mouth in fluid communication with the source and a second pressure-conduction chamber mouth in fluid communication with the first passage, such that in the empty-chamber position, the rigid housing and the second membrane define an unobstructed fluid passageway through the pressure-conduction chamber from the first to the second pressure-conduction chamber mouth.

13. A cassette according to claim 12, wherein the structure for causing relative instability in the filled-chamber position causes the second membrane, when in the filled-chamber position, to collapse in the region of the second mouth before collapsing nearer the first mouth.

14. A cassette for use in a system for controlling the flow of intravenous fluid from a source to a patient, the cassette comprising:

a rigid housing; and

a membrane disposed adjacent the rigid housing;

the rigid housing and the membrane defining a pressure-conduction chamber; wherein a pressure-conduction chamber portion of the rigid housing is generally dome-shaped, the membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is substantially at its smallest volume, and in which position the membrane rests against the rigid housing and assumes the dome shape of the pressure-conduction chamber portion of the rigid housing, the membrane having a structure for promoting a collapse of the membrane from the filled-chamber position to the empty-chamber position.

15. A cassette according to claim 14, wherein the structure may be actuated to cause relative instability in the empty-chamber position.

16. A cassette according to claim 15, wherein the pressure-conduction chamber has a first pressure-conduction chamber mouth providing fluid from the intravenous-fluid source and a second pressure-conduction chamber mouth leading to the first passage, such that in the empty-chamber position, the rigid housing and the membrane define an unobstructed fluid passageway through the pressure-conduction chamber from the first to the second pressure-conduction chamber mouth.

17. A cassette according to claim 16, wherein the structure causes the membrane, when in the filled-chamber position, to collapse in the region of the second mouth before collapsing nearer the first mouth.

18. A cassette according to claim 14, the membrane having an interior surface that comes into contact with the fluid and an exterior surface,
wherein the structure includes a tab extending from the exterior surface from a point adjacent where the rigid housing meets the membrane.

19. A cassette according to claim 14, the membrane having an interior surface that comes into contact with the fluid and an exterior surface,
wherein the membrane is molded in the empty-chamber position with the interior surface having a smooth concave dome shape corresponding to the dome shape of pressure-conduction chamber portion of the rigid housing and wherein the exterior surface having a generally convex dome shape, but further having some additional material to cause the membrane to be unstable in the filled-chamber position.

20. A cassette for use in a system for controlling the flow of intravenous fluid from a source to a patient, the cassette comprising:

a rigid housing; and

a membrane disposed adjacent the rigid housing;

the rigid housing and the membrane defining a pressure-conduction chamber;
wherein a pressure-conduction chamber portion of the rigid housing is generally dome-shaped, the membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is substantially at its smallest volume, and in which position the membrane rests against the rigid housing and assumes the dome shape of the pressure-conduction chamber portion of the rigid housing, the membrane having a structure which may be actuated to reduce resistance of the membrane to initial movement from the empty-chamber position to the filled-chamber position.

21. A cassette according to claim 20, the membrane having an interior surface that comes into contact with the fluid and an exterior surface, wherein the structure includes a tab extending from the exterior surface from a point adjacent where the rigid housing meets the membrane, wherein the tab may be urged, by an actuator in a control unit for

receiving the cassette, towards the rigid housing so as to lift a portion of the membrane away from the rigid housing.

Abstract

A cassette for use in controlling the flow of IV fluid from a patient to a source. The cassette may include along the fluid passage through the cassette, first and second membrane-based valves (**6**, **7**) on either side of a pressure-conduction chamber (**50**), and a stopcock-type valve (**20**). The stopcock valve is preferably located downstream of the second membrane-based valve (**7**), which is preferably located downstream of the pressure-conduction chamber (**50**). The membrane defining the valving chamber of the second membrane-based valve (**7**) is preferably large and resilient, so that the valving chamber (**75**) may provide a supply of pressurized intravenous fluid to the patient, when the valve (**6**) is closed and the stopcock valve (**20**) provides a restriction downstream of the valve (**7**). The pressure-conduction chamber (**50**) preferably has a membrane (**41**) that is stable in the empty-chamber position but relatively unstable in the filled-chamber position.

[122204]

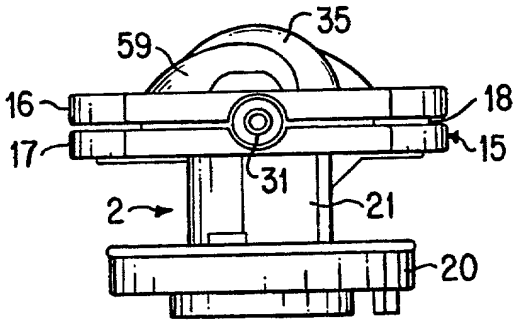

FIG. 1

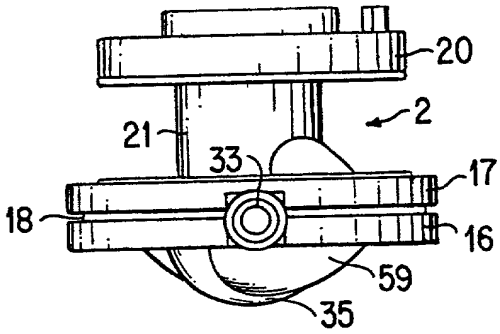

FIG. 3

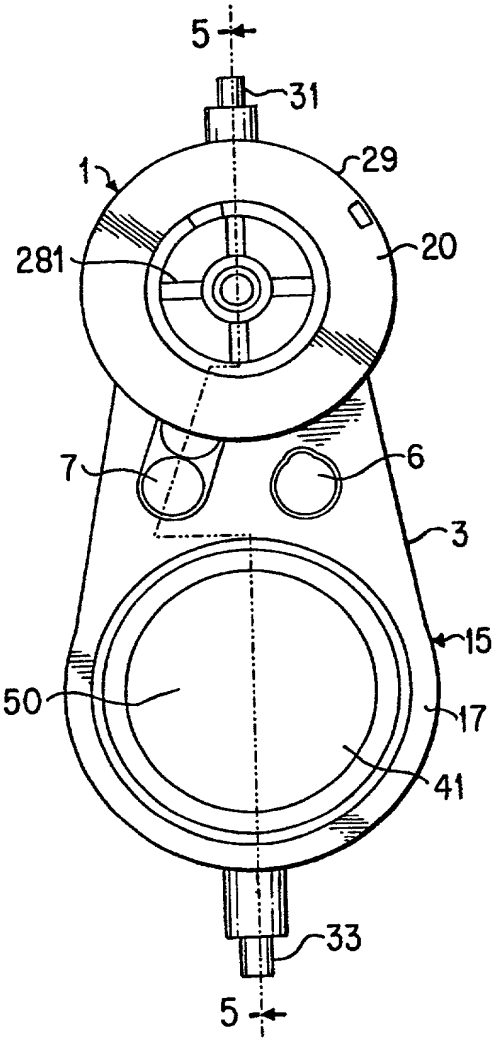

FIG. 2

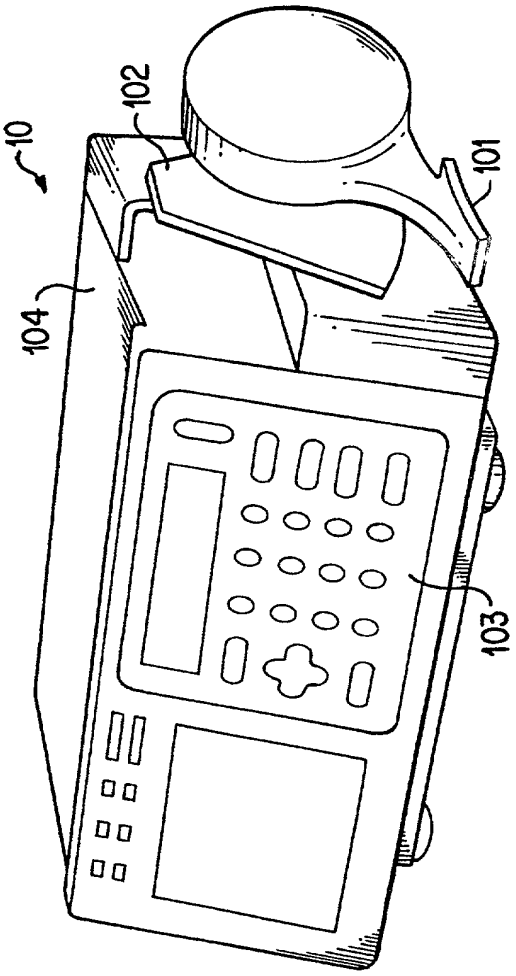

FIG. 4

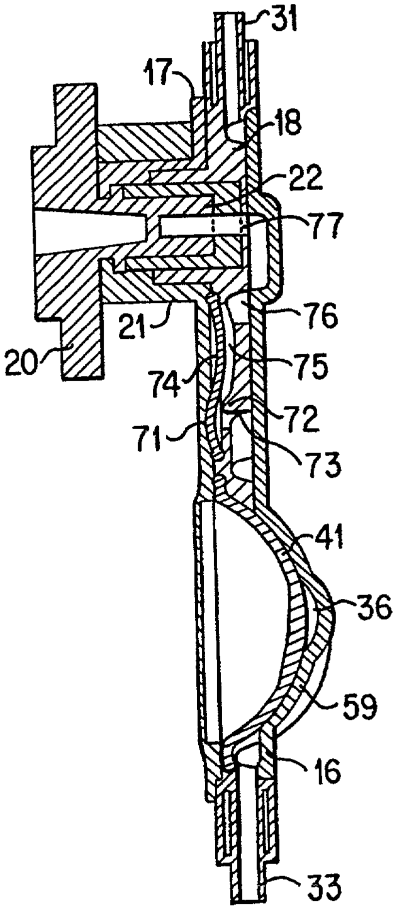
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FIG. 5

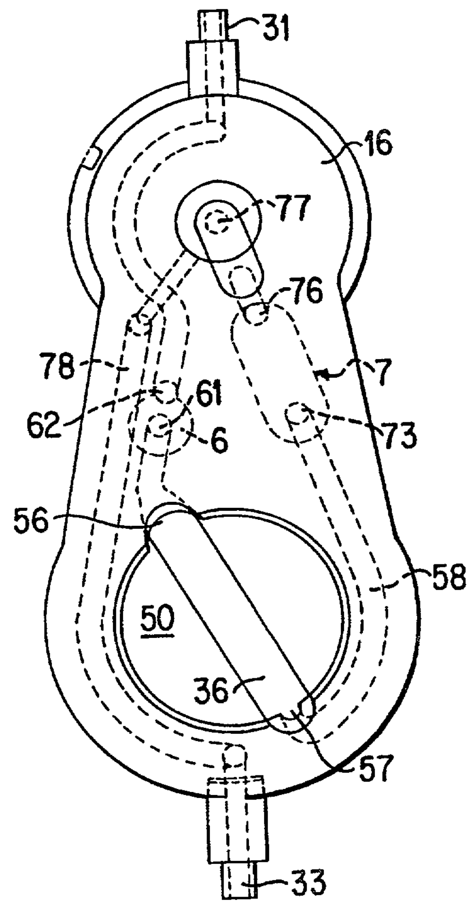
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FIG. 6

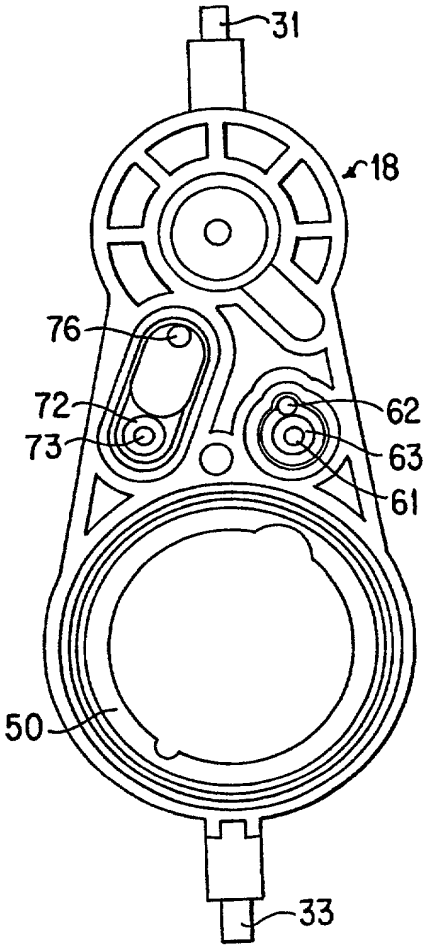

FIG. 7

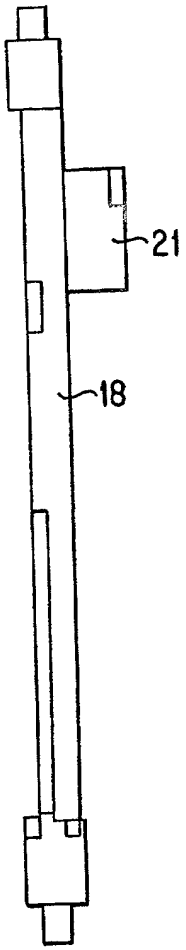

FIG. 8

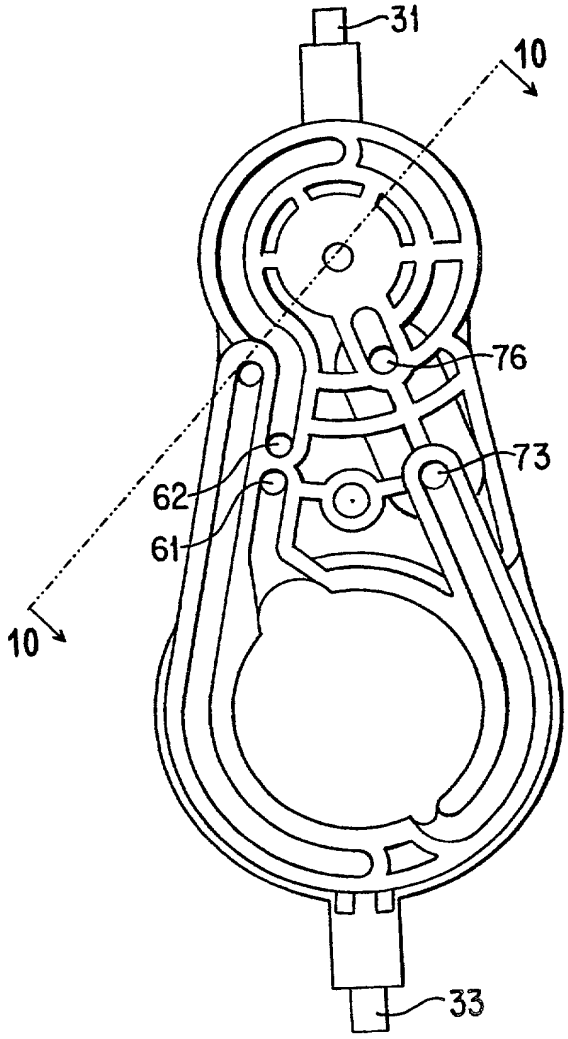

FIG. 9

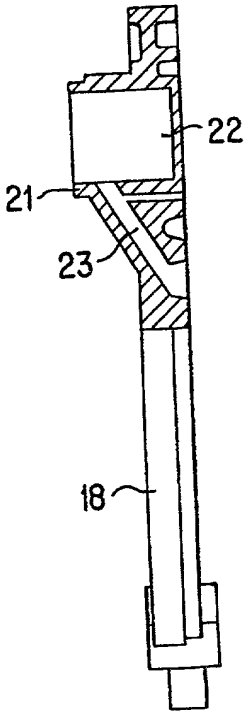

FIG. 10

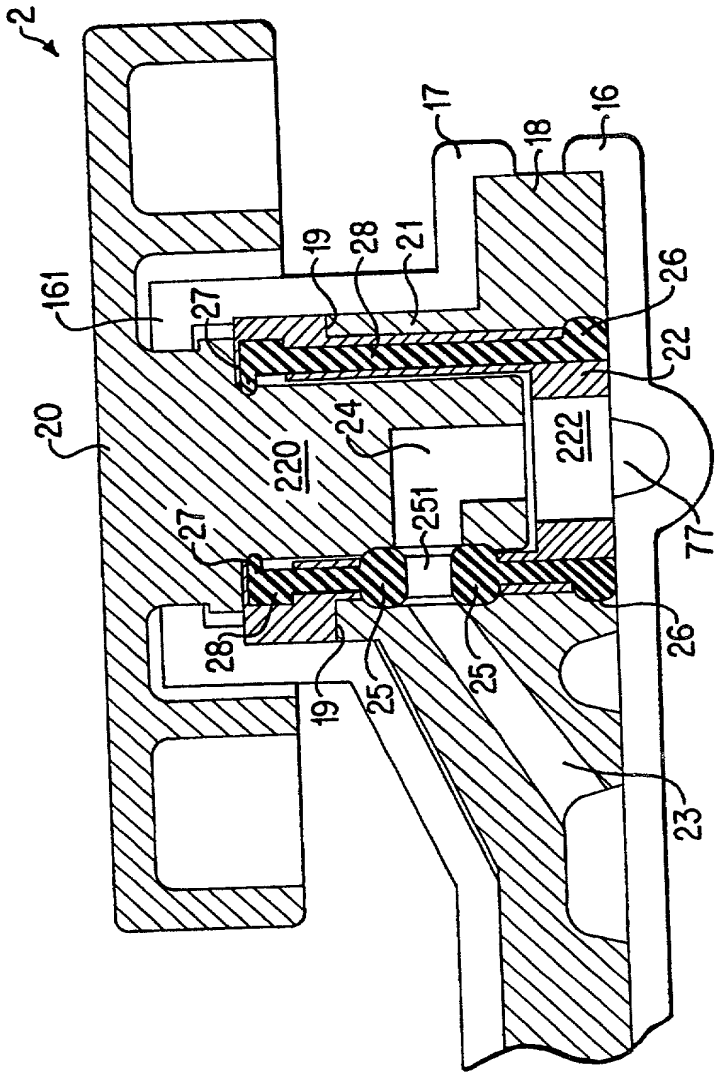

FIG. 11

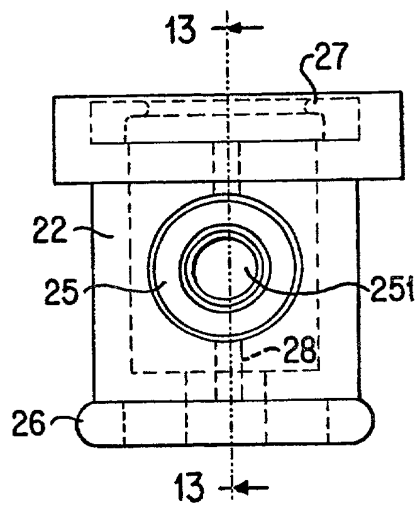

FIG. 12

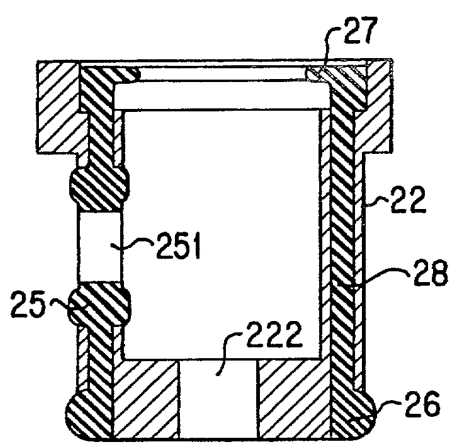

FIG. 13

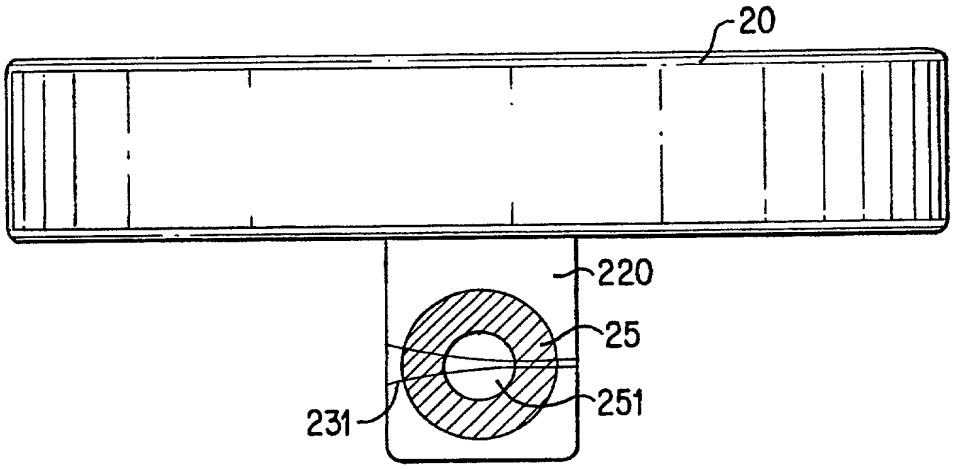

FIG. 14

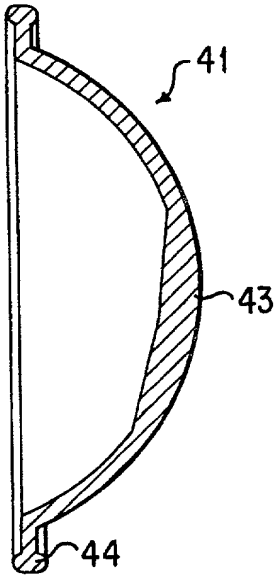

FIG. 15

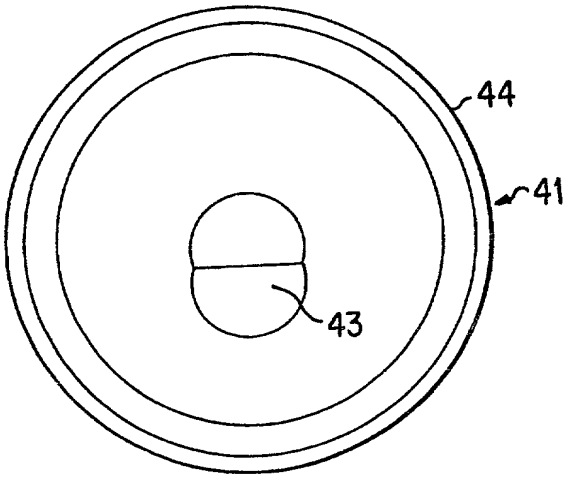

FIG. 16

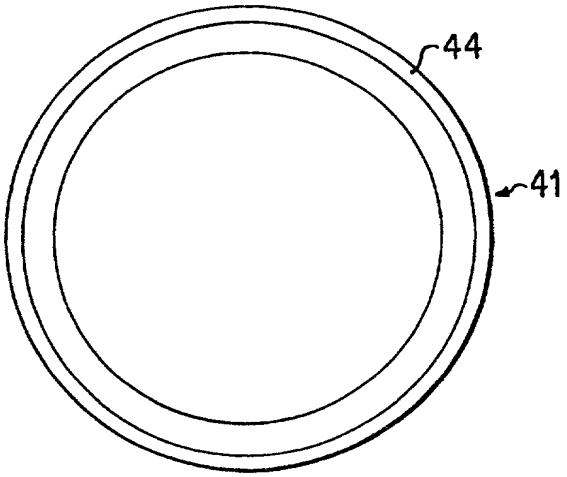

FIG. 17

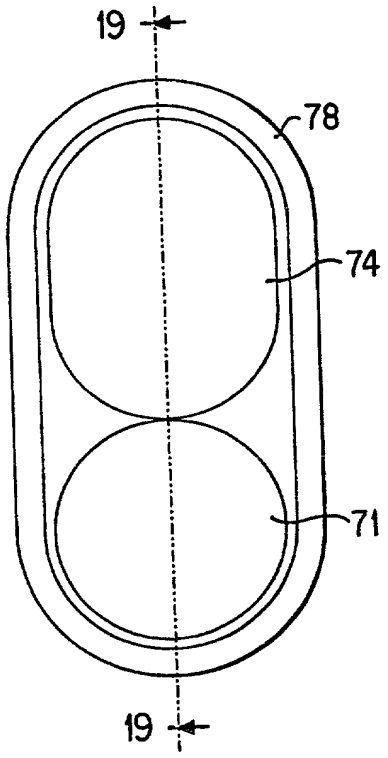

FIG. 18

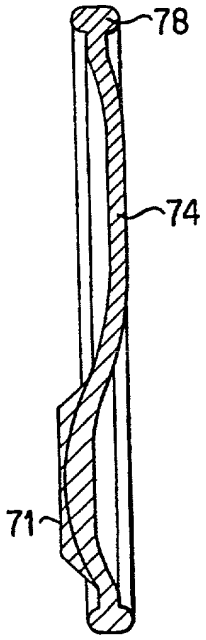

FIG. 19

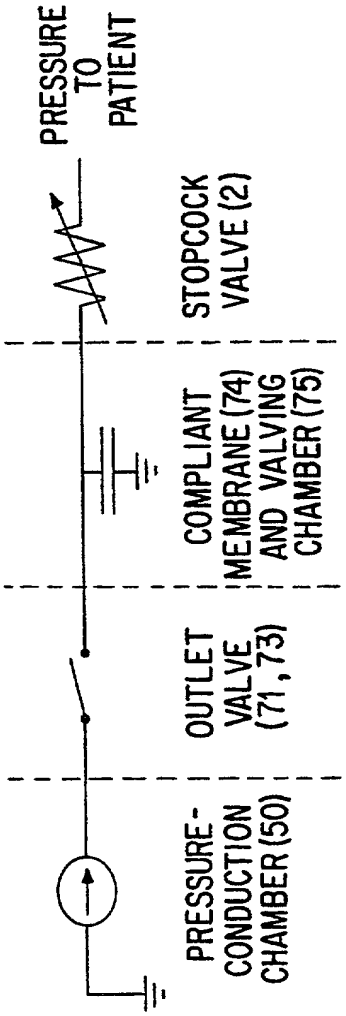
PRESSURE TO PATIENT
STOPCOCK VALVE (2)
COMPLIANT MEMBRANE (74) AND VALVING CHAMBER (75)
OUTLET VALVE (71, 73)
PRESSURE-CONDUCTION CHAMBER (50)

FIG. 20

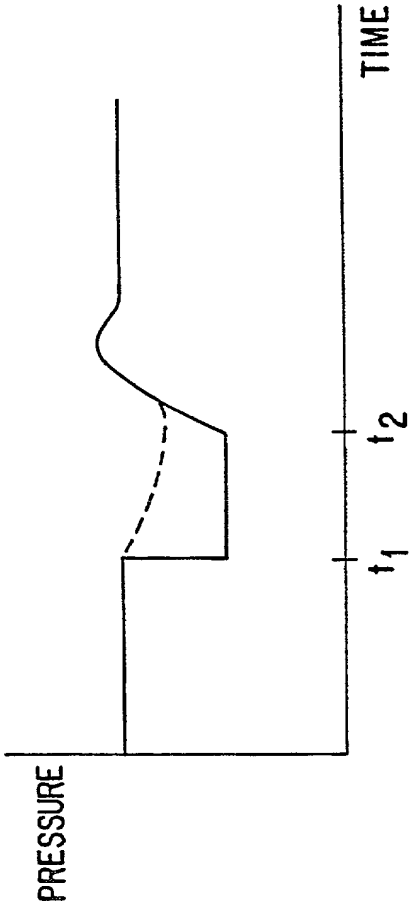
PRESSURE
TIME
t_1
t_2

FIG. 21

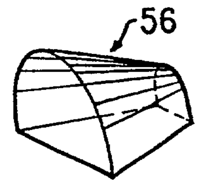

FIG. 22

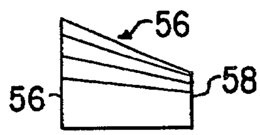

FIG. 23

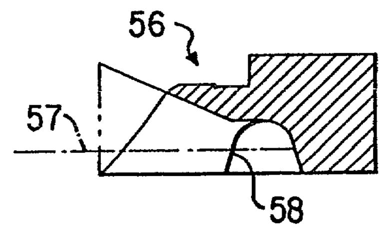

FIG. 24

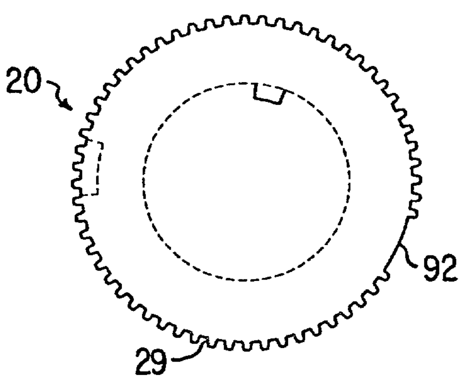

FIG. 25

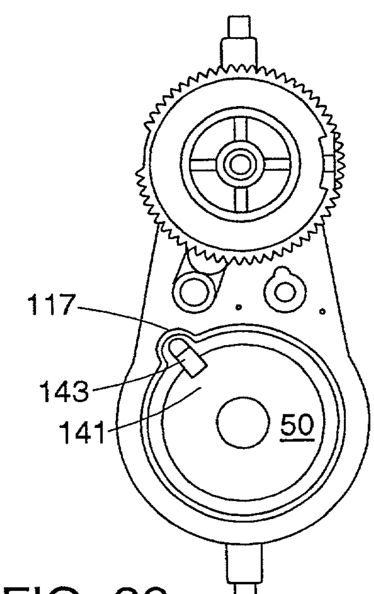

FIG. 26

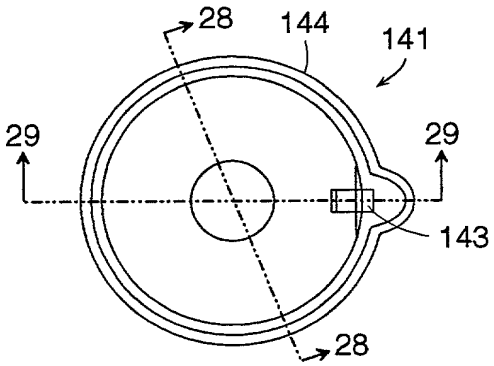

FIG. 27

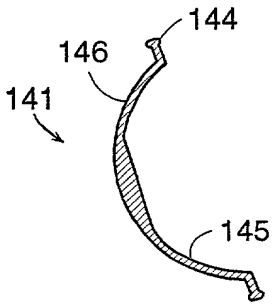

FIG. 28

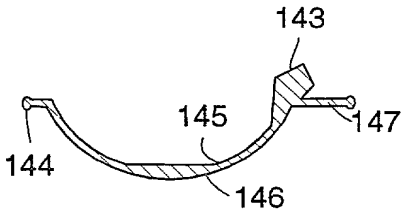

FIG. 29

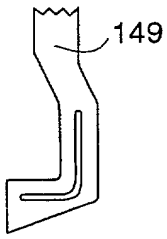

FIG. 30

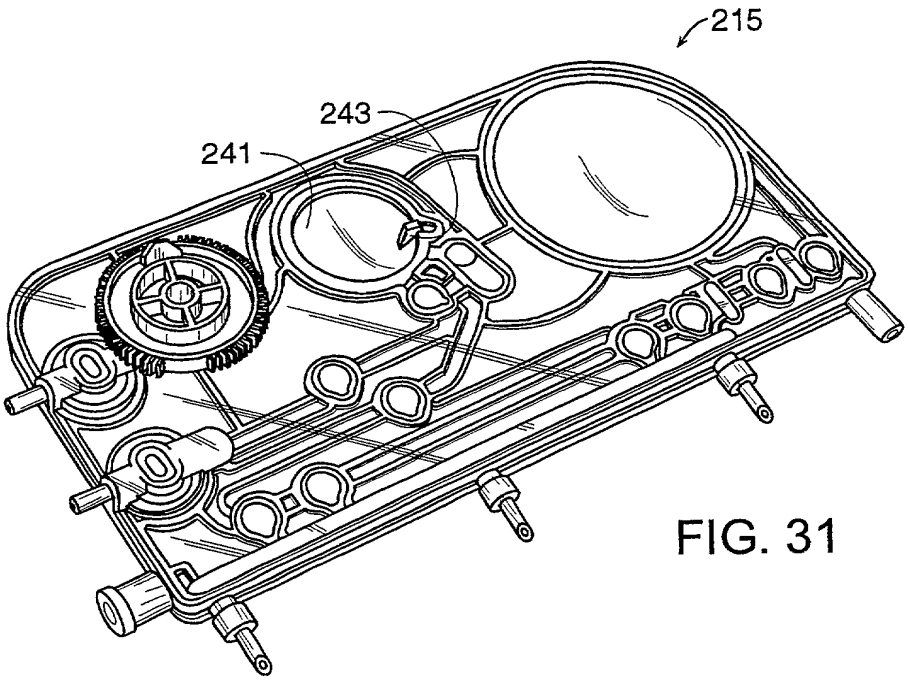

FIG. 31

Docket No.
1062/B55

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on August 22, 1997 as United States Application No. or PCT International Application Number 08/917,537

and was amended on _____
(if applicable)

DO NOT ENTER

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

08/478,065	June 7, 1995	Pending
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

Timothy M. Murphy	33,198
Bruce D. Sunstein	27,234
Robert M. Asher	30,445
Samuel D. Petuchowski	37,910
Chinh H. Pham	39,329
Harriet M. Strimpel	37,008
Steven G. Saunders	36,265

Send Correspondence to: Timothy M. Murphy
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110

Direct Telephone Calls to: *(name and telephone number)*
Timothy M. Murphy at (617) 443-9292

Full name of sole or first inventor **Larry B. Gray**
Sole or first inventor's signature: Larry B. Gray — Date: 6 Oct 97
Residence **19 Iris Drive, Merrimack, NH 03051**
Citizenship
Post Office Address

Full name of second inventor, if any **Philip Houle**
Second inventor's signature — Date
Residence **525 Homer Avenue, Apt. #8, Palo Alto, CA 94301**
Citizenship
Post Office Address

Full name of third inventor, if any **William T. Larkins**
Third inventor's signature William T Larkins Date 10/6/97
Residence **245 Carnegie Street, Manchester, NH 03104**
Citizenship USA 10/6/97
Post Office Address

Full name of fourth inventor, if any
Fourth inventor's signature Date
Residence
Citizenship
Post Office Address

Full name of fifth inventor, if any
Fifth inventor's signature Date
Residence
Citizenship
Post Office Address

Full name of sixth inventor, if any
Sixth inventor's signature Date
Residence
Citizenship
Post Office Address

Express Mail Label No.

Docket No.
1062/B55

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CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

the specification of which

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☒ was filed on August 22, 1997 as United States Application No. or PCT International Application Number 08/917,537

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Prior Foreign Application(s)			Priority Not Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
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(Application Serial No.)	(Filing Date)
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(Application Serial No.)	(Filing Date)

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(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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125 Summer Street
Boston, MA 02110

Direct Telephone Calls to: *(name and telephone number)*
Timothy M. Murphy at (617) 443-9292

Full name of sole or first inventor
Larry B. Gray

Sole or first inventor's signature — Date
Larry B. Gray — 6 Oct 97

Residence
19 Iris Drive, Merrimack, NH 03051

Citizenship

Post Office Address

Full name of second inventor, if any
Philip Houle

Second inventor's signature — Date
Philip R. Houle — 2/13/98

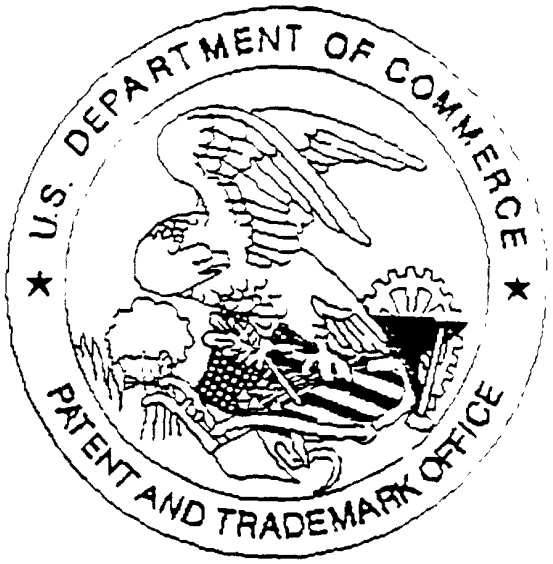
Residence
525 Homer Avenue, Apt. #8, Palo Alto, CA 94301

Citizenship

Post Office Address

United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division



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